In the United States Court of Federal Claims

No. 15-247 V
Filed: August 15, 2018

JASMYNE GRAMZA, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	*	National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 to -34; Vaccine Rules of the United States Court of Federal Claims 4 (Respondent's Review of Petitioner's Records), 18 (Availability of Filings), 23 (Motion for Review), 27 (Reviewing a Decision of the Special Master).

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Darryl R. Wishard, United States Department of Justice, Civil Division, Washington, D.C., Counsel for Respondent.

MEMORANDUM OPINION AND FINAL ORDER[1]

BRADEN, *Senior Judge.*

Petitioner[2] requests review of the Special Master's February 5, 2018 Decision[3] ("2/5/2018 Decision"), denying an award under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 to -34 (2012) (the "Vaccine Act").

[1] On July 31, 2018, the court forwarded a sealed copy of this Memorandum Opinion And Final Order to the parties to redact any confidential and/or privileged information from the public version by August 14, 2018, pursuant to Vaccine Rule 18(b). Neither Petitioner nor Respondent proposed redactions.

[2] Petitioner's mother filed this action on behalf of Petitioner, who was a minor on March 10, 2015. ECF No. 1 at 1. The caption then read "TARAH GRAMZA, on behalf of her minor child, J.G.," and Petitioner was referred to as "J.G." ECF No. 1 at 1. On December 20, 2017, after Petitioner reached the age of majority, the Special Master issued an Order instructing the Clerk of the United States Court of Federal Claims ("Clerk of Court") to change the caption to reflect Petitioner's name, "JASMYNE GRAMZA." ECF No. 74.

[3] The unredacted Decision of the Special Master was issued on February 5, 2018. ECF No. 75. The redacted, public version of the Decision was issued on April 2, 2018. ECF No. 79.

To facilitate review of this Memorandum Opinion And Final Order, the court has provided the following outline.

Because this court's review relies on the entirety of the record before the Special Master, this Memorandum Opinion And Final Order refers to the unredacted February 5, 2018 Decision.

I. RELEVANT FACTUAL AND PROCEDURAL BACKGROUND.

A. Medical History.[4]

On January 17, 2012, Jasmyne Gramza ("Petitioner") received the first dose of the three-dose Human Papillomavirus vaccination ("HPV vaccine" or "Gardasil").[5] Pet. Ex. 3 at 10, 30–31. At that time, Petitioner was twelve years old. Pet. Ex. 3 at 29. Petitioner was allergic to chlorophyll and had a history of migraine headaches, dating back to at least 2010, but otherwise had no other chronic medical complaints. Pet. Ex. 3 at 29–31, 37, 43.

On July 26, 2012, Petitioner received a second dose of the HPV vaccine while being treated for a large hematoma[6] on her leg from a fall two months earlier. Pet. Ex. 3 at 10, 25–26. Petitioner's physician recommended that Petitioner place a heating pad on the "slightly tender" bruise that remained, monitor the situation, and return within four months for her final dose of the HPV vaccine. Pet. Ex. 3 at 25–26. On January 23, 2013, Petitioner received a third dose of the HPV vaccine. Pet. Ex. 3 at 10, 20.

On February 11, 2014, Petitioner visited her primary care physician, Dr. Trupti Amin-Chapman, for a checkup. Pet. Ex. 3 at 13. Petitioner reported that in the past six months, she bruised more easily and those bruises seemed disproportionately large, relative to the injuries that

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[4] The relevant facts were derived from Petitioner's Exhibits 3–4 ("Pet. Exs. 3–4"), the Entitlement Hearing Transcript, dated June 6, 2017, ECF No. 68 ("6/6/2017 TR at 1–172"), and the Entitlement Hearing Transcript, dated June 7, 2017, ECF No. 70 ("6/7/2017 TR at 173–357").

[5] "Papillomavirus" is "any virus of the family papillomaviridae." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1372 (32d ed. 2012) ("DORLAND'S"). "Human papillomavirus" is "any of a number of species of papillomaviruses that cause warts, particularly plantar and genital warts, on the skin and mucous membranes in humans." *Id.* at 1373. "Gardasil" is a "trademark for a preparation of human papillomavirus quadrivalent vaccine, recombinant." DORLAND'S at 761. "Human papillomavirus quadrivalent vaccine, recombinant" is

> a quadrivalent vaccine prepared from the virus like particles of the major capsid protein of human papillomavirus types 6, 11, 16, and 18, which are responsible for the great majority of cases of condyloma acuminatum and cervical cancer; administered intramuscularly to girls and young women between the ages of 9 and 26 for the prevention of condyloma acuminatum and neoplastic diseases caused by susceptible types.

Id. at 2016.

[6] A "hematoma" is "a localized collection of blood, usually clotted, in an organ, space, or tissue, usually due to a break in the wall of a blood vessel." DORLAND'S at 832.

caused them. Pet. Ex. 3 at 15. Petitioner's physician ordered a blood test, that showed Petitioner's platelet count[7] was below the reference range and her prothrombin time ("PTT") was higher than the reference range.[8] Pet. Ex. 3 at 17, 76–77.

On February 13, 2014, Petitioner was examined by Dr. Christine Knoll, a hematologist,[9] who performed additional blood testing. Pet. Ex. 4 at 86, 88. The results were normal, except for Epstein–Barr Virus ("EBV") titers,[10] that suggested a past infection. Pet. Ex. 4 at 88. Dr. Knoll concluded that Petitioner's condition was possibly autoimmune[11] and, if so, likely lupus.[12] Pet.

[7] A "platelet" is "a disk-shaped structure, . . . found in the blood of all mammals and chiefly known for its role in blood coagulation." DORLAND'S at 1459. A "platelet count" is a "determination of the number of platelets per cubic millimeter of blood; it may be either a *direct platelet count* with a hemacytometer and a microscope or an *indirect platelet count* in which the ratio of platelets to erythrocytes on a blood smear is determined and the number of platelets determined from the erythrocyte count." *Id.* at 425 (italics in original).

[8] "Prothrombin" is "a plasma protein that is converted to the active form thrombin . . . in the common pathway of coagulation; thrombin then cleaves fibrinogen to its active form fibrin. Deficiency of the factor leads to hypoprothrombinemia." DORLAND'S at 674. "Prothrombin time" is "the rate at which prothrombin is converted to thrombin in citrated blood with added calcium," and is "used to assess the extrinsic pathway of coagulation." *Id.* at 1928.

[9] "Hematology" is "the branch of medical science that deals with the blood and blood-forming tissues." DORLAND'S at 832. A "hematologist" is "a specialist in hematology." *Id.*

[10] "Epstein-Barr Virus" is "a virus of the genus *Lymphocryptovirus* that causes infectious mononucleosis and is associated with Burkitt lymphoma and nasopharyngeal carcinoma." DORLAND'S at 2061. A "titer" is "the quantity of a substance required to produce a reaction with a given volume of another substance, or the amount of one substance required to correspond with a given amount of another substance." *Id.* at 1932.

[11] "Autoimmune" describes phenomena "characterized by a specific humoral or cell-mediated immune response against constituents of the body's own tissues (self antigens or autoantigens)." DORLAND'S at 181.

[12] "Lupus" is "1. the name formerly given to numerous types of localized destruction or degeneration of the skin caused by cutaneous diseases," or "2. [lupus] erythematosus," that is "a group of connective tissue disorders primarily affecting women aged 20 to 40 years, comprising a spectrum of clinical forms in which cutaneous disease may occur with or without systemic involvement." DORLAND'S at 1079. "Cutaneous lupus erythematosus may involve only the skin or may precede involvement of other body systems." *Id.* "Systemic lupus erythematosus" is a "chronic, inflammatory, often febrile multisystemic disorder of connective tissue[. It] may be either acute or insidious in onset and is characterized principally by involvement of the skin . . . , joints, kidneys, and serosal membranes. The condition is marked by a wide variety of abnormalities, including . . . thrombocytopenia, hemolytic anemia, . . . and the presence in the blood of distinctive cells called LE cells." *Id.* at 1080.

Ex. 4 at 88 ("I discussed at length with the family that this is [an] autoimmune process, wich [*sic*] concerns for lupus . . . . I do think she needs to be further worked up with anti-phospholipid syndrome with lupus anticoagulant.").[13] Dr. Knoll recommended that Petitioner avoid contact sports and gym class, and take Tylenol instead of ibuprofen or aspirin for any aches, pains, or fevers.[14] Pet. Ex. 4 at 88.

On February 16, 2014, Petitioner noticed petechiae[15] and went to the emergency room. Pet. Ex. 4 at 81–82. A blood test revealed that Petitioner's platelet count was still low, as the previous test had shown, and Petitioner was discharged. Pet. Ex. 4 at 82.

On February 21, 2014, Petitioner was examined by Dr. Kaleo Ede, a rheumatologist.[16] Pet. Ex. 3 at 59–61. Dr. Ede conducted an exam with normal results. Pet. Ex. 3 at 61. Dr. Ede noted

[13] "Antiphospholipid antibody" refers to "a group of antibodies against phosphorylated polysaccharide esters of fatty acids, thought to be markers of a hyper-coagulable state of the blood; included are anticardiolipin antibodies and lupus anticoagulant." DORLAND'S at 101. "Antiphospholipid antibody syndrome" refers to "a multisystem inflammatory disorder characterized by the presence of circulating antiphospholipid antibodies with thrombosis (including thrombotic microangiopathy), spontaneous abortion, thrombocytopenia, valvular heart disease, and other less frequent symptoms. A severe type called catastrophic antiphospholipid syndrome is characterized by infarctions of several different organs and is often fatal." *Id.* at 1821.

[14] Tylenol is a "trademark for preparations of acetaminophen." DORLAND'S at 1992. "Acetaminophen" is "the amide of acetic acid and *p*-aminophenol, having analgesic and antipyretic effects similar to aspirin's but only weak anti-inflammatory effects." *Id.* at 12. "Ibuprofen" is "a nonsteroidal anti-inflammatory drug derived from propionic acid and having also analgesic and antipyretic actions; administered orally in the treatment of pain, fever, dysmenorrhea, osteoarthritis, rheumatoid arthritis, and other rheumatic and nonrheumatic inflammatory disorders, and in the treatment and prophylaxis of vascular headaches." *Id*. at 910. "Aspirin" is "acetylsalicylic acid, a drug having anti-inflammatory, analgesic, and antipyretic effects; it is the prototype of the nonsteroidal anti-inflammatory drugs whose mechanism of action is inhibition of prostaglandin synthesis; used for relief of pain, fever, and inflammation and for treatment of arthritis, osteoarthritis, and rheumatic fever. Because it is a platelet inhibitor, it is also used to reduce the risk of recurrent transient ischemic attacks, stroke syndrome, thromboembolism following certain surgical procedure, and initial or recurrent myocardial infarction." *Id.* at 166.

[15] A "petechia" (singular of petechiae) is "a pinpoint, nonraised, perfectly round, purplish red spot caused by intradermal or submucous hemorrhage." DORLAND'S at 1422.

[16] A "rheumatologist" is "a specialist in rheumatic conditions." DORLAND'S at 1639. "Rheumatism" describes "any of a variety of disorders marked by inflammation, degeneration, or metabolic derangement of connective tissue structures of the body, especially the joints and related structures, including muscles, bursae, tendons, and fibrous tissue, with pain, stiffness, or limitation of motion." *Id.*

that Petitioner recently was diagnosed with thrombocytopenia,[17] but she "[did] not meet criteria for systemic lupus erythematosus at [that] time;" he recommended that Petitioner receive a further evaluation for lupus. Pet. Ex. 3 at 60, 61.

On an unspecified date thereafter, Petitioner was examined by Dr. Sanjay Shah, a hematologist in the same practice as Dr. Knoll. Pet. Ex. 4 at 69–72. This time, Petitioner's platelet count no longer was low. Pet. Ex. 4 at 69, 72. Dr. Shah reviewed Petitioner's hematology lab results with Petitioner and her mother, noting that Petitioner had a prolonged PTT, normal iron studies, a negative Coombs test,[18] and a positive antibody[19] screen. Pet. Ex. 4 at 71. These tests were "suggestive of a lupus anticoagulant,"[20] but Dr. Shah did not diagnose Petitioner with lupus; instead, his diagnosis was chronic immune thrombocytopenic purpura[21] ("ITP"). Pet. Ex. 4 at 71–72. Dr. Shah discussed the normal course of treatment for ITP with Petitioner's mother, but did not prescribe any treatment pending further observation and the results of additional testing ordered by Dr. Ede. Pet. Ex. 4 at 72.

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[17] "Thrombocytopenia" is "a decrease in the number of platelets, such as in thrombocytopenic purpura." DORLAND'S at 1922.

[18] A "Coombs test" is an "antiglobulin test," that is

> a test for the presence of nonagglutinating antibodies against red blood cells, using antihuman globulin antibody to agglutinate cells coated with the nonagglutinating antibody. The *direct antiglobulin test* detects antibodies bound to circulating red cells in vivo. It is used in the evaluation of autoimmune and drug-induced immune hemolytic anemia and erythroblastosis fetalis. The *indirect antiglobulin test* detects serum antibodies that bind to red cell in an in vitro incubation step. It is used in typing of erythrocyte antigens and in compatibility testing (cross-match).

DORLAND'S at 1885, 1888 (italics in original).

[19] An "antibody" is "an immunoglobulin molecule that has a specific amino acid sequence by virtue of which it interacts only with the antigen that induced its synthesis . . . or with antigen closely related to it. Antibodies are classified in groups according to their mode of action." DORLAND'S at 100.

[20] "Lupus anticoagulant" is "a circulating anticoagulant that inhibits the conversion of prothrombin to thrombin, found in 5-10 per cent of patients with systemic lupus erythematosus, but also seen in other disorders." DORLAND'S at 102.

[21] "Immune thrombocytopenic purpura" is "a type of thrombocytopenic purpura that is not directly associated with any definable systemic disease but often follows a systemic infection; it has been found to be an autoimmune condition, caused by antigens against platelets, resulting in ecchymoses, petechiae, and other bleeding. There are both acute and chronic forms: the *acute form* has a sudden onset, is more common in children, and usually resolves spontaneously within a few months; the *chronic form* has a slower onset, is more common in adults, and may be recurrent." DORLAND'S at 1557 (emphases in original).

On March 28, 2014, Petitioner returned to Dr. Shah for another evaluation. Pet. Ex. 4 at 56–59. Petitioner and her parents reported that Petitioner had new, "not excessively large" bruises, and experienced fatigue, joint pain, and sore muscles. Pet. Ex. 4 at 57. Dr. Shah believed that Petitioner's ITP was most likely autoimmune in origin, based on her test results indicating lupus anticoagulant. Pet. Ex. 4 at 58. Dr. Shah, however, did not believe that Petitioner was at risk for significant bleeding, because her platelet count had risen to 34,000.[22] Pet. Ex. 4 at 59. Because Petitioner still reported "significant" fatigue, Dr. Shah informed Petitioner's mother of treatment options for chronic ITP and noted that he would discuss those options with Dr. Ede and other colleagues. Pet. Ex. 4 at 59.

On April 30, 2014, Petitioner was examined by Dr. Ede for a "follow[-]up [regarding] her abnormal antibodies." Pet. Ex. 4 at 50–52. Petitioner reported weekly nosebleeds, bleeding gums after brushing her teeth, spontaneous bruising, a particularly heavy menstrual period, fatigue, and occasional joint pain. Pet. Ex. 4 at 50. Dr. Ede noted that Petitioner's exam results from that day were normal, but considering all of Petitioner's lab results in and after February 2014, concluded that Petitioner had "ITP with consistent thrombocytopenia." Pet. Ex. 4 at 51. In addition, Dr. Ede found that Petitioner met three of eleven classification criteria for systemic lupus erythematosus ("SLE"), but did not diagnose Petitioner with lupus, because a patient must meet four of the criteria to be diagnosed. Pet. Ex. 4 at 51. Dr. Ede declined to make any specific treatment recommendations, pending further testing and decisions by Petitioner's hematologists, but noted that Petitioner "likely need[ed] treatment for her thrombocytopenia." Pet. Ex. 4 at 51.

On May 14, 2014, Petitioner sought urgent care after experiencing two nosebleeds in one day and two weeks of heavy menstruation. Pet. Ex. 4 at 46–47. Petitioner's platelet count was then 13,000 and her hemoglobin count[23] was 10.6. Pet. Ex. 4 at 47. Petitioner was discharged, but planned to schedule an appointment with a hematologist the next day. Pet. Ex. 4 at 47.

On May 15, 2014, Petitioner was examined by Dr. James Williams, a hematologist, who confirmed Petitioner's low platelet count and noted that her thrombocytopenia was "worsening." Pet. Ex. 4 at 44. Dr. Williams discussed treatment options with Petitioner and her parents and began Petitioner on a course of intravenous immunoglobulin[24] ("IVIG") therapy. Pet. Ex. 4 at 44.

During a follow-up visit with Dr. Williams on May 21, 2014, Petitioner's platelet count increased to 135,000. Pet. Ex. 4 at 40. On May 29, 2014, Plaintiff returned to the office, where she was examined by Drs. Williams, Knoll, and Shah for an "urgent add[-]on visit due to increased

[22] According to Petitioner's medical chart, the reference range for platelet count is 140,000–450,000. Pet. Ex. 4 at 54.

[23] "Hemoglobin" is "the red oxygen-carrying pigment of erythrocytes, formed by developing erythrocytes in bone marrow." DORLAND'S at 839. According to Petitioner's medical chart, the reference range for hemoglobin is 11.0–15.0. Pet. Ex. 4 at 48.

[24] "Immunoglobulin" refers to "any of the structurally related glycoproteins that function as antibodies, divided into five classes . . . on the basis of structure and biologic activity." DORLAND'S at 919. "Intravenous" describes activity "within a vein or veins." *Id.* at 954.

petechiae and bleeding." Pet. Ex. 4 at 38. They noted a significant drop in Petitioner's platelet count, that was 21,000, and administered another dose of IVIG. Pet. Ex. 4 at 38. After a discussion with Petitioner's parents, Petitioner received a prescription for four doses of Rituxan.[25] Pet. Ex. 4 at 38.

On June 17, 2014, Plaintiff visited with Dr. Williams again and Petitioner's platelet count dropped to 4,000. Pet. Ex. 4 at 23. Dr. Williams prescribed a four-day course of oral steroids and administered the third dose of the four-dose Rituxan regimen. Pet. Ex. 4 at 23. Dr. Williams also noted that Petitioner had received a Depo-Provera[26] shot for her heavy menses two weeks prior. Pet. Ex. 4 at 23.

On June 27, 2014, Petitioner's platelet count increased to 76,000. Pet. Ex. 4 at 21. At the end of July 2014, Petitioner's platelet count increased to 225,000, a normal count. Pet. Ex. 4 at 13. By the end of August 2014, Petitioner's platelet count decreased to 176,000, but was still within the normal range. Pet. Ex. 4 at 9. By December 2014, Dr. Williams also noted that her platelet count had been normal since July. Pet. Ex. 4 at 2.

B. Procedural History.

On March 10, 2015, Petitioner's mother filed a Petition seeking compensation under the National Vaccine Injury Compensation Program. ECF No. 1. On March 12, 2015, Special Master Corcoran (the "Special Master") entered an Initial Order directing Petitioner to "begin filing medical records relevant to her claim as promptly as possible." ECF No. 5 at 1. On March 24, 2015, Petitioner filed a Statement And Medical Records. ECF No. 7.

On May 15, 2015, Petitioner's mother filed updated medical records. ECF No. 11. On May 26, 2015, the Government filed a Report, pursuant to Vaccine Rule of the United States Court of Federal Claims 4(c), together with a number of academic and news articles, recommending that compensation be denied and the March 10, 2015 Petition be dismissed. ECF No. 12.

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[25] "Rituxan" is a "trademark for a preparation of rituximab." DORLAND'S at 1650. "Rituximab" is "a chimeric murine/human monoclonal antibody that binds the DC 20 antigen; used as an antineoplastic in the treatment of CD20-positive, B-cell non-Hodgkin lymphoma; administered intravenously." *Id.*

[26] "Depo-Provera" is a "trademark for preparation of medroxyprogesterone acetate." DORLAND'S at 492. "Medroxyprogesterone acetate" is

> a progestin administered orally for treatment of secondary amenorrhea and dysfunctional uterine bleeding, induction of menses, prevention and treatment of endometrial hyperplasia in postmenopausal hormone replacement therapy, and testing for endogenous estrogen production; administered orally or intramuscularly as an antineoplastic in treatment of metastatic endometrial, breast, and renal carcinoma; and administered intramuscularly as a long-acting contraceptive.

Id. at 1120.

On June 2, 2015, the Special Master convened a status conference. Minute Entry dated 6/4/2015.

On August 3, 2015, Petitioner filed a Motion For An Extension Of Time, requesting additional time to submit an expert report. ECF No. 14. On August 4, 2015 that motion was granted.[27] Minute Entry dated 8/4/2015. On August 10, 2015, Petitioner filed additional medical records. ECF No. 15. On August 17, 2015, Petitioner filed an Expert Report and Curriculum Vitae for Dr. Shoenfeld. ECF No. 16. On August 19, 2015, the Government filed a Status Report And Request To Set Deadlines, requesting that the Special Master set a deadline of December 4, 2015, for the Government to file an expert report. ECF No. 17 at 1. The Government also requested that Petitioner "file the pertinent medical literature to be relied on by Dr. Shoenfeld." ECF No. 17 at 1. On August 20, 2015, Petitioner filed a Response To Respondent's Request To Set Deadlines, without objection to the Government's request and agreeing that it would file Dr. Shoenfeld's medical literature "upon receipt." ECF No. 18 at 1. On August 26, 2015, the Special Master convened a status conference. Minute Entry dated 8/27/2015. During that status conference, Petitioner requested that the court strike the Expert Report filed on August 17, 2015 from the record, because it did not include a "relevant section of the expert's analysis." ECF No. 19. On August 27, 2015, the Special Master issued an Order, directing the Clerk of Court to strike Petitioner's Expert Report from the record and Petitioner to file a revised or complete version of the Expert Report. ECF No. 19. Petitioner filed a corrected Expert Report that same day. ECF No. 20.

On September 22, 2015, Petitioner filed medical literature referenced in Dr. Shoenfeld's Expert Report. ECF Nos. 21–26.

On November 2, 2015, the Special Master issued a formal notice,[28] notifying the parties that "[t]he statutory 240-day period for the special master's issuance of a decision in this case expired," and Petitioner could elect to withdraw the March 10, 2015 Petition or continue to remain in the program. ECF No. 27. On November 23, 2015, the Government filed the Expert Reports and Curricula Vitae of Drs. Rose and Forsthuber, together with supporting reference documents. ECF Nos. 28–30. The Government also filed Respondent's Amendment To Vaccine Rule 4(c) Report, averring that the evidence in all three Expert Reports supported a diagnosis of SLE, instead of antiphospholipid antibody syndrome. ECF No. 31 at 1.

[27] The Special Master did not assign a CM/ECF number to this Order, instead entering it directly onto the docket as a "Non-PDF Order."

[28] Under 42 U.S.C. § 300aa-12(d)(3)(a)(ii), a Special Master is required to issue a decision on a Vaccine Program petition "not later than 240 days . . . after the date the petition was filed." *Id.* If a Special Master does not issue a decision within that period, he or she is required to notify the petitioner that the petitioner may either withdraw the petition or elect to have the petition remain before the Special Master. 42 U.S.C. § 300aa-12(g).

On February 1, 2016, Petitioner filed the Rebuttal Expert Report of Dr. Shoenfeld and additional medical literature. ECF Nos. 32–35. On February 22, 2016, the Special Master held a third status conference and issued an Order directing the Government to file a responsive Expert Report by April 29, 2016. Minute Entries dated 2/22/2016.[29]

On March 23, 2016, the Government filed an Expert Opinion Supplemental Report from Dr. Rose, together with supporting documentation. ECF Nos. 36–38.

On April 7, 2016, the Special Master convened a status conference and issued a Scheduling Order. Minute Entries dated 4/7/2016.[30] That Scheduling Order directed Petitioner to file a status report by April 29, 2016, indicating whether she wished to file a Supplemental Expert Report from Dr. Shoenfeld. Second Minute Entry dated 4/7/2016. The Scheduling Order also directed the parties to confer and schedule an entitlement hearing for April, May, or June of 2017, and to indicate whether they believed a settlement would be possible. Second Minute Entry dated 4/7/2016. On April 29, 2016, Petitioner filed a Status Report stating that: (1) the Government advised Petitioner that it was "not interested in pursuing settlement discussions at [that] time;" (2) Petitioner would not submit a Supplemental Expert Report from Dr. Shoenfeld or any other expert; and (3) the parties would be available for an entitlement hearing during the first week of June 2017. ECF No. 39.

On May 13, 2016, the Special Master convened a status conference. Minute Entry dated 5/13/2016. On May 18, 2016, the Special Master issued a Pre-Hearing Order setting the entitlement hearing for June 6–7, 2017. ECF No. 40.

On June 2, 2016, Petitioner submitted photographic evidence. ECF No. 41. On that same day, Petitioner also filed a Status Report explaining that Petitioner's Exhibit 89 was "offered to demonstrate that insidious bruising due to ITP was present, at the latest, by May 29, 2012." ECF No. 42 at 1.

On July 26, 2016, Petitioner filed additional medical documentation. ECF No. 43. On August 17, 2016, Petitioner filed a Status Report, explaining that Petitioner's Exhibit 90 was a journal article, authored by Dr. Shoenfeld, with a "focus" on "[Petitioner's] vaccine induced ITP and antiphospholipid antibodies following administration of the HPV vaccine." ECF No. 44 at 1. The Status Report explained that Exhibit 90 was submitted to "demonstrate the reliability of Petitioner's causation-in-fact theory." ECF No. 44 at 3.

On October 11, 2016, Petitioner filed a letter from her treating physician. ECF No. 45. On October 12, 2016, Petitioner filed updated laboratory results from Phoenix Children's Medical Group. ECF No. 46.

[29] The Special Master did not assign a CM/ECF number to this Scheduling Order, instead entering it directly onto the docket as a "Non-PDF Scheduling Order."

[30] The Special Master did not assign a CM/ECF number to this Scheduling Order, instead entering it directly onto the docket as a "Non-PDF Scheduling Order."

On February 22, 2017, Petitioner filed a Pre-Hearing Submission And Witness And Exhibit List. ECF No. 50.

On March 7, 2017, the Special Master issued a Scheduling Order granting a request from the Government for leave to file "an additional piece of medical literature out of time." Minute Entry dated 3/7/2017.[31] On March 9, 2017, the Government filed additional medical research. ECF No. 51. On March 15, 2017, the Government filed Respondent's Pre-Hearing Brief. ECF No. 52.

On April 21, 2017, Petitioner filed additional medical research and Petitioner's Reply To Respondent's Pre-Hearing Submission. ECF Nos. 53–54. On April 28, 2017, the Government filed additional medical research. ECF No. 55. On May 12, 2017, Petitioner filed a Statement on her own behalf. ECF No. 56. On May 23, 2017, Petitioner filed a demonstrative exhibit. ECF No. 57.

On June 2, 2017, Petitioner filed additional demonstrative exhibits. ECF No. 58. On June 6–7, 2017, the Special Master conducted an entitlement hearing in Washington, D.C. First Minute Entry dated 6/7/2017; 6/6/17 TR at 1–172; 6/7/17 TR at 173–357. On June 7, 2017, following the entitlement hearing, the Special Master issued a Scheduling Order directing the parties to file any demonstrative exhibits or literature that was referenced during the hearing, but not filed with the Special Master, by June 23, 2017. Second Minute Entry dated 6/7/2017.[32] The Scheduling Order also directed the parties to confer and decide whether they would file post-trial briefs by June 23, 2017. Second Minute Entry dated 6/7/2017. On June 8, 2017, the Government filed medical research and expert documents. ECF No. 59. On June 14, 2017, Petitioner filed an Application For Interim Attorneys' Fees And Costs. ECF No. 60. On June 15, 2017, Petitioner filed additional medical research and expert documentation. ECF No. 61. On that same day, the Government filed a Response To Petitioner's Application For Interim Attorneys' Fees And Costs. ECF No. 62.

On June 16, 2017, Petitioner filed a Status Report, informing the Special Master that the parties proposed to file simultaneous post-trial briefs forty-five days after the hearing transcript was filed. ECF No. 63 at 1. The Special Master entered a Scheduling Order reflecting that and ordering the parties to file their briefs on or before August 15, 2017. Second Minute Entry dated 6/16/2017.[33] On June 28, 2017, the Special Master entered a Decision Granting Interim Award Of Attorney's Fees And Costs. ECF No. 64. On July 6, 2017, the parties filed a Joint Notice Not To Seek Review Of The Decision Granting Interim Award Of Attorney's Fees And Costs, and the Clerk of Court entered an Order awarding fees and costs to Petitioner in the amount specified by the Special Master. ECF Nos. 65–66.

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[31] The Special Master did not assign a CM/ECF number to this Scheduling Order, instead entering it directly onto the docket as a "Non-PDF Scheduling Order."

[32] The Special Master did not assign a CM/ECF number to this Scheduling Order, instead entering it directly onto the docket as a "Non-PDF Scheduling Order."

[33] The Special Master did not assign a CM/ECF number to this Scheduling Order, instead entering it directly onto the docket as a "Non-PDF Scheduling Order."

On July 6, 2017, the transcript of the entitlement hearing was filed. ECF Nos. 68, 70.

On August 15, 2017, Petitioner filed a Post-Hearing Submission and the Government filed Respondent's Post-Hearing Brief. ECF Nos. 71–72. On August 17, 2017, the Special Master filed a second Decision Granting Interim Award Of Attorney's Fees And Costs. ECF No. 73.

On December 20, 2017, the Special Master filed an Order directing the Clerk of Court to change the case caption to reflect Petitioner reaching the age of majority. ECF No. 74.

On February 5, 2018, the Special Master issued a Decision Denying Entitlement. ECF No. 75.

On March 7, 2018, Petitioner filed a Motion For Review of the Special Master's February 5, 2018 Decision, pursuant to Vaccine Rule 23 ("Pet. Mot."). ECF No. 76. Petitioner also filed a Memorandum Of Objections In Support Of The Motion For Review ("Pet. Mem."). ECF No. 77.

On April 5, 2018, the Government filed Respondent's Response To Petitioner's Motion For Review ("Gov't Resp."). ECF No. 80. On April 12, 2018, Petitioner filed a Motion For Leave To File Reply Brief. ECF No. 81. On April 16, 2018, the Government filed a Response To Petitioner's April 12, 2018 Motion. ECF No. 82. On April 17, 2018, Petitioner filed a Reply To Respondent's Response To Petitioner's April 12, 2018 Motion. ECF No. 83.

On May 9, 2018, the court entered an Order granting Petitioner's Motion For Leave To File Reply Brief. ECF No. 84. On May 10, 2018, Petitioner filed a Reply ("Pet. Reply"). ECF No. 85.

C. The March 10, 2015 Petition.

On March 10, 2015, Petitioner's mother filed a Petition ("March 10, 2015 Petition" or "3/10/2015 Pet.") on behalf of Petitioner for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 to -34 ("Vaccine Program"). 3/10/2015 Pet. at 1. The March 10, 2015 Petition alleged that the three doses of the HPV vaccine, administered on January 7, 2012, July 26, 2012, and January 23, 2013, caused Petitioner's antiphospholipid antibody syndrome and thrombocytopenia. 3/10/2015 Pet. at 1.

The March 10, 2015 Petition also alleged that "by March of 2013, [Petitioner] was bruising abnormally easily," though her mother did not feel the situation merited medical attention until January 2014 when Petitioner's blood was tested, revealing an "extremely low" platelet count. 3/10/2015 Pet. at 1–2. Petitioner received a diagnoses of ITP and "an antiphospholipid issue" on February 11, 2014; after "intervention therapy" of "IGG, Rituximab, and steroids," Petitioner's platelet count returned to normal and she remained in remission. 3/10/2015 Pet. at 2. And, Petitioner is at a high risk for chronic ITP and her "ability to function in society is severely impaired" by her ITP symptoms, which were caused either by the HPV vaccine directly, or by her "antiphospholipid issue," which in turn was caused by the HPV vaccine. 3/10/2015 Pet. at 2.

The March 10, 2015 Petition further alleged that there is "ample scientific evidence connecting [Petitioner's] symptomology and her vaccinations" and supporting her conclusion that her medical "complaints" were "caused-in-fact by the Gardasil vaccinations." 3/10/2015 Pet. at

2, 3. The March 10, 2015 Petition cited articles from medical journals that purportedly evidenced: (1) a causal connection between viral and other vaccinations and the production of antiphospholipid antibodies; (2) a link between antiphospholipid antibodies and thrombocytopenia; and (3) a "direct[ ]" causal link between the HPV vaccine and ITP. 3/10/2015 Pet. at 2–3.

The March 10, 2015 Petition also alleged that Petitioner had not brought any civil action for damages nor received any settlement or other award for her "vaccine-related injury." 3/10/2015 Pet. at 8. The March 10, 2015 Petition sought damages for "pain and suffering [Petitioner] . . . experienced as a result of her adverse reaction, as well as economic damages and damages in the future." 3/10/2015 Pet. at 8.

D. The Entitlement Hearing Before The Special Master.

On June 6–7, 2017, the Special Master conducted an entitlement hearing in Washington, D.C. *See generally* 6/6/2017 TR at 1–172; 6/7/2017 TR at 173–357. Petitioner, her mother, and Dr. Ede testified as witnesses. 6/6/2017 TR at 3. Both parties also presented expert witnesses. 6/6/2017 TR at 3; 6/7/2017 TR at 175.

1. Fact Witnesses.

a. Petitioner's Mother.

Petitioner's Mother testified that Petitioner showed no immediate signs of an adverse reaction after receiving the first dose of the HPV vaccine in January 2012. 6/6/2017 TR at 10. A few months later, however, Petitioner fell onto her hip on a pool deck resulting in a "massive bruise that didn't heal for many, many months." 6/6/2017 TR at 10–11. After Petitioner received the second dose of the HPV vaccine, Petitioner's mother noticed no new signs, but the hematoma Petitioner received from the pool deck fall "didn't really heal like . . . you would expect it to heal." 6/6/2017 TR at 11. After Petitioner received the third dose of the HPV vaccine, "nothing stood out," but "around the timeframe of March [Petitioner's mother] started noticing little bruises" on Petitioner's shins and elbows. 6/6/2017 TR at 12. When Petitioner continued to notice painless bruising in June 2013, she began taking iron supplements. 6/6/2017 TR at 12–13.

In July 2013, Petitioner, her mother, and their family took a trip to Hawaii. 6/6/2017 TR at 13. Petitioner's mother testified that during the flight to Hawaii, Petitioner began to menstruate heavily and "bled out [onto] the chair and . . . had to get up and change during the flight." 6/6/2017 TR at 13. While in Hawaii, Petitioner developed a painless bruise on the back of her leg, "three or four" inches in diameter, from falling off a soft-sided boat. 6/6/2017 TR at 13–14. Petitioner's mother "didn't . . . really think anything serious was wrong." 6/6/2017 TR at 14–15. During the summer of 2013, Petitioner was "really tired" and "would fall asleep pretty early," and continued to bruise easily. 6/6/2017 TR at 15.

Petitioner's mother "finally" took Petitioner to see a doctor when Petitioner developed two large hematomas on the backs of her legs after falling off of her parents' bed onto a dresser. 6/6/2017 TR at 15–16. At the end of a "well checkup," Petitioner's mother informed Dr. Amin-Chapman that Petitioner was bruising easily. 6/6/2017 TR at 16. Dr. Amin-Chapman "sent [them] off to the lab" for testing and called the next morning with results showing that Petitioner's

platelets were low. 6/6/2017 TR at 16–17. When Petitioner was examined by specialists, Petitioner's mother reported Petitioner's medical history, although she was not aware that Petitioner also experienced nosebleeds. 6/6/2017 TR at 17. Next, Petitioner was examined by Dr. Ede, who ran more laboratory tests, including a urine test, and examined Petitioner's joints. 6/6/2017 TR at 18–19. Dr. Ede "was looking for a particular joint pain or some sort of kidney involvement . . . to see if there was any kind of lupus present," but did not find that evidence, and did not diagnose Petitioner with lupus. 6/6/2017 TR at 19.

In 2014, Petitioner developed increased petechiae and continued to experience fatigue and menstrual hemorrhaging. 6/6/2017 TR at 19–20. Petitioner's platelet count rose and fell repeatedly; when it fell below 10,000 she experienced nosebleeds and "other symptoms." 6/6/2017 TR at 19–20. She received a Depo-Provera shot to stop hemorrhaging. 6/6/2017 TR at 20.

After Petitioner's symptoms diminished, her mother began to research what had caused Petitioner's condition. 6/6/2017 TR at 21–22. She found "a lot of support for vaccine-induced" causation. 6/6/2017 TR at 22. In particular, she shared research by Dr. Ede with Petitioner's treating physicians, Dr. Ede and Dr. Williams, but "they were unable to share, by their legal team, the opinion of whether or not the vaccine was the cause." 6/6/2017 TR at 23.

Petitioner's mother testified that she did not remember telling Dr. Amin-Chapman about Petitioner taking iron supplements during the February 2014 checkup. 6/6/2017 TR at 26–27. Petitioner's mother provided a medical chart during the February 11, 2014 checkup with Dr. Amin-Chapman. 6/6/2017 TR at 30–31. During that visit, Petitioner's mother told Dr. Amin-Chapman that Petitioner's menstruation was normal and Petitioner was not experiencing "nosebleeds [n]or excessive bleeding with periods," because she "didn't know" that Petitioner experienced either condition. 6/6/2017 TR at 31. Petitioner's mother also did not tell Dr. Amin-Chapman about Petitioner's bruising from the pool deck or the boat in Hawaii. 6/6/2017 TR at 31–32. Petitioner's mother also testified that in February 2013, she was unaware of "any problems [Petitioner experienced] with her gums." 6/6/2017 TR at 34.

Petitioner's mother and her husband went with Petitioner to an appointment with Dr. Knoll on February 13, 2014. 6/6/2017 TR at 35, 36. There, Dr. Knoll was advised that "[t]hey started noticing significant bruising over the [prior] . . . six to eight months," or "at least as far back as July 2013." 6/6/2017 TR at 36. Petitioner's mother also mentioned "spontaneous bruising," but did not recall "anything . . . about any problems that [Petitioner] may have had with heavy menses." 6/6/2017 TR at 38. Petitioner's mother told Dr. Knoll that the family's babysitter had been sick with mononucleosis, and that Petitioner had shown no symptoms of mononucleosis at that time. 6/6/2017 TR at 39. Petitioner had pneumonia "probably a year or so before she . . . got the [HPV vaccine] shots." 6/6/2017 TR at 39.

Petitioner's mother mentioned Petitioner's fatigue to Drs. Amin-Chapman and Knoll prior to Petitioner's February 21, 2014 appointment with Dr. Ede. 6/6/2017 TR at 40. Petitioner's mother first became aware that Petitioner experienced bleeding gums when brushing her teeth "around th[e] timeframe" of that February 21, 2014 appointment. 6/6/2017 TR at 41.

During an appointment on February 25, 2014, Petitioner's mother told Dr. Shah[34] that Petitioner experienced bruising during the previous six to eight months. 6/6/2017 TR at 41. Petitioner's mother explained that Dr. Shah's note did not reflect any gum or mouth bleeding, despite Dr. Ede's note to the contrary, testifying that "[Petitioner] probably was the one who communicated with Dr. Ede a little bit more," while Dr. Shah "was more interactive with the parents and less with the child." 6/6/2017 TR at 41–42. For example, Petitioner's mother recalled that Dr. Shah examined Petitioner's skin and reported it was "normal, no bruises." 6/6/2017 TR at 42.

At Petitioner's final appointment with Dr. Ede, Petitioner's "additional symptoms of nosebleeds and bleeding gums when brushing her teeth, spontaneous bruising," and menstrual periods requiring nine pads a day were noted. 6/6/2017 TR at 44. These symptoms were all "new symptoms between the first and second visit with Dr. Ede," because Petitioner's platelet count was lower by the time of the second visit. 6/6/2017 TR at 44. By the time of that visit, Petitioner was diagnosed with "chronic ITP." 6/6/2017 TR at 44–45.

In July or August of 2014, Petitioner's mother testified that Petitioner's ITP subsided "after several rounds of Rituximab." 6/6/2017 TR at 45. Petitioner's most recent appointment with a hematologist was in September 2016, but Petitioner was scheduled to visit a hematologist again in September 2017. 6/6/2017 TR at 46. Petitioner was "doing well," with the exception of getting "headaches every once in a while." 6/6/2017 TR at 46.

In July of 2012 Petitioner had a doctor's appointment, but Petitioner's mother did not show the physician, Dr. Gardner, a photograph of the hematoma from Petitioner's May 2012 pool deck fall. 6/6/2017 TR at 47. Dr. Gardner prescribed no treatment for the two-month-old injury, but noted: the "[b]ruising ha[d] faded but . . . [left] a large swollen area on [Petitioner's] left thigh [with o]ccasional tenderness." 6/6/2017 TR at 48. Petitioner iced and bandaged the hematoma "right away" and complained for "several months" about the injury. 6/6/2017 TR at 48. Petitioner's mother testified that she did not raise any concerns about Petitioner's bleeding or iron levels with Dr. Gardner during that July 2012 appointment. 6/6/2017 TR at 49.

Petitioner's mother did not remember showing photos of Petitioner's bruising to any of Petitioner's physicians. 6/6/2017 TR at 49. She also noted that Dr. Amin-Chapman made a "vaccine exemption" note on her records. 6/6/2017 TR at 50. After treatment, Petitioner's symptoms were "resolved largely," although she was at risk for blood clots, because she carried some antiphospholipid antibodies. 6/6/2017 TR at 55.

b. Petitioner's Testimony.

Next, Petitioner testified that she never had "issues" with bleeding, abnormal bruising, or fatigue prior to receiving the first HPV vaccination in January 2012. 6/6/2017 TR at 57–58. The hematoma Petitioner experienced in May 2012, from falling on a pool deck, never healed

[34] The June 6, 2017 transcript refers to "Dr. Shaw" instead of the Dr. Shah who contributed to Petitioner's medical records. The court has corrected the spelling herein.

"completely." 6/6/2017 TR at 58. She experienced no new symptoms after the second HPV vaccination in July 2012, but following the third HPV vaccination in January 2013, she "continued to bruise and . . . had hemorrhaged periods, bleeding gums[,] and nosebleeds." 6/6/2017 TR at 60.

When Petitioner began menstruating in March 2013, her menses were "really light." 6/6/2017 TR at 61. She told her mother about her easy bruising prior to June 2013, but her mother thought she was "being dramatic." 6/6/2017 TR at 61–62. Petitioner's family moved to a new house in June 2013, that was "important," "[b]ecause it [gave her] a timeframe for when events started happening." 6/6/2017 TR at 62. During the plane ride to Hawaii, Petitioner "completely bled through her entire outfit" and a menstrual pad in two hours. 6/6/2017 TR at 63. She testified that she "just thought this was the new normal," and recalled changing her menstrual pad around nine times a day during that trip. 6/6/2017 TR at 63–64. She also testified about falling off the soft-sided boat, but it "[d]idn't hurt at all," but resulted in a "big bruise." 6/6/2017 TR at 64.

Petitioner's menses were "irregular" after the Hawaii trip, but each time she menstruated for longer than a week. 6/6/2017 TR at 64. In December 2013, she also experienced a "really bad" nosebleed during which her nose "started flowing blood like a faucet." 6/6/2017 TR at 64–65. Petitioner did not tell her parents at the time, because she "didn't know at that point that it was a big deal." 6/6/2017 TR at 65. Petitioner's gums began to bleed "probably about the same timeframe," but she did not tell anyone. 6/6/2017 TR at 65–66.

Petitioner and her parents were "finally prompted" to seek medical advice after she fell off her parents' bed onto a nightstand in February 2014. 6/6/2017 TR at 66. She had a "regular checkup" with Dr. Amin-Chapman and at the end of the appointment reminded her mother to ask about "bruising." 6/6/2017 TR at 66. After that appointment, Petitioner's blood was drawn for testing; the next day her mother took her out of school "really early." 6/6/2017 TR at 67.

By July 2014, Petitioner testified that none of her treating doctors told her that she had lupus. 6/6/2017 TR at 67. Her platelet count came "under control" in approximately July 2014. 6/6/2017 TR at 67–68.

Petitioner did not mention her heavy periods to Dr. Amin-Chapman in February 2013, because "it was embarrassing" and she did not know she was experiencing anything abnormal. 6/6/2017 TR at 71. Petitioner explained that her mother never mentioned Petitioner's heavy menstruation to Dr. Amin-Chapman, because her mother did not know the full extent of the hemorrhaging. TR at 72. Petitioner also did not mention her nosebleeds or gum bleeding to her mother, because she "thought they were normal." 6/6/2017 TR at 72. Petitioner could not recall if she had specifically told Dr. Amin-Chapman about her bruising from falling off the boat. 6/6/2017 TR at 72–73.

In February 2014, Petitioner's parents told Dr. Knoll, the first hematologist to examine her, that they noticed her bruising "about six to eight months prior." 6/6/2017 TR at 73. Petitioner "probably" mentioned the boat fall to Dr. Knoll. 6/6/2017 TR at 73–74.

Petitioner testified that when her leg made contact with the side of the pool when she fell in May 2012, it had been "more of a slide than a bump;" she confirmed that she did not visit a doctor about the resulting injury until July 2012. 6/6/2017 TR at 74–75. Petitioner bandaged her leg for "[p]robably two, three months," but otherwise "continued [her] normal activity," but the hematoma remained. 6/6/2017 TR at 75.

c. Dr. Kaleo Ede's Testimony.

Dr. Kaleo Ede, a rheumatologist who examined Petitioner in 2014, also testified. 6/6/2017 TR at 115–16. He reviewed his notes from his appointment with Petitioner on February 21, 2014, when he recorded that Petitioner complained of "six months of gradually worsening fatigue," years of headaches and poor sleep, "mild bleeding of gums when she was brushing her teeth," and "easy bruising." 6/6/2017 TR at 117. Her laboratory tests "showed thrombocytopenia." 6/6/2017 TR at 117–18. Petitioner did not complain to Dr. Ede of joint pain and she had no trouble with range of motion in her joints. 6/6/2017 TR at 118. Dr. Ede found Petitioner to meet three of the diagnostic criteria for lupus—"hematologic criteria, thrombocytopenia, a positive ANA[,] and a positive double strand of DNA"—but did not meet the criteria for a lupus diagnosis. 6/6/2017 TR at 118.[35] Petitioner's kidney function was "normal," that was important in Dr. Ede's decision not to diagnose Petitioner with lupus, because "kidney involvement is one of the three most common clinical manifestations in lupus." 6/6/2017 TR at 118–19.

Dr. Ede's second appointment with Petitioner was on April 30, 2014. 6/6/2017 TR at 119. He noted that Petitioner's symptoms included nosebleeds "once or twice a week, bleeding gums with teeth brushing, spontaneous bruising, and heavy menstrual periods." 6/6/2017 TR at 119–20. Petitioner reported that her fatigue "improved." 6/6/2017 TR at 120. She reported "occasional joint pain," but no swelling, and Dr. Ede noted no issues with her range of joint motion. 6/6/2017 TR at 120. Dr. Ede did not find that Petitioner met the criteria for lupus, in part because Petitioner continued to show "normal" kidney function. 6/6/2017 TR at 120–21. He did not opine on her diagnosis of ITP, because it was "out of the scope of [his] practice . . . to diagnose and treat ITP." 6/6/2017 TR at 122. Dr. Ede did not examine Petitioner after May 2014. 6/6/2017 TR at 123.

[35] Dr. Ede diagnosed Petitioner using diagnostic criteria for lupus promulgated by the American College of Rheumatology ("ACR") in 1997. 6/6/2017 TR at 121. He chose to use those criteria, because the 1997 ACR criteria were "the most widely used classification criteria for diagnosing pediatric patients with lupus." 6/6/2017 TR at 121. As of the day of his testimony, the 1997 ACR criteria were the only set of criteria endorsed by the ACR on its website. 6/6/2017 TR at 121. He was aware of an alternative set of criteria called the Systemic Lupus International Collaborating Clinics ("SLICC") criteria, that were promulgated in 2012. 6/6/2017 TR at 121; *see also* ECF No. 28-3 at 4 (Gov't Ex. G, introducing the 2012 SLICC criteria). He did not know whether the ACR had endorsed the use of those criteria in evaluating patients for lupus. 6/6/2017 TR at 121. Dr. Ede testified that in 2017 his "personal practice" was "more towards the use of the SLICC criteria," because more data supported their validity in children. 6/6/2017 TR at 121–22.

Dr. Ede confirmed that in 2017 he more frequently used the SLICC diagnostic criteria in evaluating children for lupus, but the SLICC criteria were available in 2014 when he examined Petitioner. 6/6/2017 TR at 123. If he had used the SLICC criteria to evaluate Petitioner in 2014, Petitioner would have met four of those criteria: thrombocytopenia, antinuclear antibodies, anti-DNA, and antiphospholipid antibodies. 6/6/2017 TR at 123–24.

Dr. Ede concluded that he took "the clinical picture of a patient" into account in diagnosing lupus, as well as either version of the diagnostic criteria. 6/6/2017 TR at 124–25. Both the 1997 ACR criteria and the 2012 SLICC criteria primarily were intended as "classification criteria used to enroll patients in studies," but they were also used to "guide and help with diagnosis in the clinic." 6/6/2017 TR at 125. Petitioner's only "clinical criteri[on]" for lupus was her ITP diagnosis. 6/6/2017 TR at 125. The 1997 ACR criteria, however, were "validated" for adults. 6/6/2017 TR at 125. The 1997 ACR criteria were "never . . . adopted officially by the ACR as pediatric-specific criteria," but were the subject of several studies that "show[ed] validation." 6/6/2017 TR at 126. The 2012 SLICC criteria were also validated. 6/6/2017 TR at 126.

The Special Master asked Dr. Ede whether ITP was an "indicia or a sign" of lupus. 6/6/2017 TR at 126. Dr. Ede explained that "thrombocytopenia or low platelets" was a symptom of lupus, but that ITP is a separate disease. 6/6/2017 TR at 127.

2. Petitioner's Expert—Dr. Shoenfeld.

Dr. Yehuda Shoenfeld is the head of the autoimmune center at the Sheba Medical Center of Tel Aviv University in Tel Aviv, Israel. 6/6/2017 TR at 79–80. He has published more than one hundred peer-reviewed articles and one textbook on the subject of vaccination and autoimmune disease. 6/6/2017 TR at 80. Dr. Shoenfeld also has published more than ten papers on ITP, including on its link to vaccines; was "among the first" to publish on antiphospholipid antibodies and antiphospholipid syndrome; and has published "[m]any papers" on rheumatological diseases, including lupus. 6/6/2017 TR at 80–81. He holds the title of Master of the ACR, an honor given by the American College of Rheumatology to those who have "contribute[d] significantly to the world of rheumatology[,] both in science and clinical work." 6/6/2017 TR at 82. Dr. Shoenfeld testified as an expert witness in the areas of immunology, rheumatology, and autoimmune disease. 6/6/2017 TR at 82–83.

Dr. Shoenfeld described the operation of ITP and autoimmune diseases and testified that the "clinical manifestation [is] . . . a tendency for bleeding," as "determined by the number of platelets which are destructive." 6/6/2017 TR at 85. "[P]unctuate bleeding," or purpura, "might be the first sign" of ITP, potentially followed by bruising "without any external cause" and "severe bleeding [ ] into the brain or . . . other important organs." 6/6/2017 TR at 85. But, the number of platelets required to produce such effects is not the same in every patient: for example, one patient with 100,000 platelets might experience bleeding symptomatic of ITP, while a chronic ITP patient with only 30,000 platelets might not experience bleeding. 6/6/2017 TR at 85–86.

Dr. Shoenfeld testified that the onset timing of ITP is not the same for every patient: "[i]t may take weeks and sometimes it may take months and sometimes it may take years." 6/6/2017 TR at 86. Childhood ITP has "more of an acute presentation," where symptoms "may appear in a few weeks or a few months;" in contrast, adult ITP "may take . . . many months," and may only be discovered when a physician performs a blood test for a different purpose. 6/6/2017 TR at 86.

Although there is a "big difference" in onset timing between childhood ITP and adult ITP, Dr. Shoenfeld did not distinguish onset timing for adult ITP with an adolescent, but emphasized that an adolescent or an adult would typically have a "more chronic . . . incubation time" than a child. 6/6/2017 TR at 87–88.

Dr. Shoenfeld explained that thrombocytopenia was the fourth most common side effect of all vaccines, and that ITP specifically has been linked to "infectious agents," including those introduced to the body by vaccines. 6/6/2017 TR at 88–90. This occurs through a process called "molecular mimicry,"[36] whereby a vaccine's structural similarity to the virus or bacteria it protects against can induce ITP. 6/6/2017 TR at 90. Dr. Shoenfeld testified about a March 26, 2009 "Letter to the Editor," published in the journal *Vaccine,* focusing on the fact that "HPV joined the long list of vaccines which may cause thrombocytopenia." 6/6/2017 TR at 91. Although this letter discussing a possible causal relationship between the HPV vaccine and thrombocytopenia was not peer reviewed as of the date of his testimony, Dr. Shoenfeld also discussed an upcoming peer-reviewed publication and data collected that supported his August 14, 2015 conclusion. 6/6/2017 TR at 93–94.

In addition, Dr. Shoenfeld testified about the operation of antiphospholipid antibodies, including anticardiolipin, antibeta-2, and lupus anticoagulant, that "can come together with ITP quite frequently," though they also are associated with lupus. 6/6/2017 TR at 130–32. Dr. Shoenfeld testified that he was not aware of any research linking antiphospholipid antibodies to the HPV vaccine, but he was aware that other vaccines have been associated with the onset of antiphospholipid syndrome and a group of researchers from Serbia published a "series of six or seven papers" suggesting that the tetanus vaccine can induce antiphospholipid syndrome and antiphospholipid antibodies through the process of molecular mimicry. 6/6/2017 TR at 133. Dr. Shoenfeld also emphasized that "potentially HPV can induce autoantibodies from the group of antiphospholipid antibodies," without being "connected to the underlying disease" of antiphospholipid syndrome. 6/6/2017 TR at 134.

Dr. Shoenfeld agreed with Petitioner's treating physicians that Petitioner did not have lupus, based on his review of her medical records, her treatment, and his observation of Petitioner at the time of his testimony. 6/6/2017 TR at 135–37. Although the Rituximab regimen Petitioner received could have prompted a remission, if Petitioner had lupus, Petitioner would not have remained in remission three years later, if Rituximab was the only treatment she received. 6/6/2017 TR at 138–39.

Next, Dr. Shoenfeld discussed his view of the timing of Petitioner's symptoms. TR at 140–43. Dr. Shoenfeld did not agree that Petitioner must show symptoms within one or two months of the ITP's onset, because generally the first change caused by ITP is a drop in platelet numbers, that may not be immediately observable. 6/6/2017 TR at 141. Usually, ITP is noticeable only once a sudden, severe drop in platelets causes bleeding or when external trauma causes bleeding and a hematoma, as occurred in Petitioner's case. 6/6/2017 TR at 141–42. Dr. Shoenfeld

[36] "Molecular mimicry" is "an occurrence in which sequence similarities between foreign (e.g., pathogens) and self-peptides are sufficient to result in the cross-activation of autoreactive T or B cells. [It is] [b]elieved to play a role in the pathogenesis of diseases of the central nervous system and other autoimmune diseases." MOSBY'S MEDICAL DICTIONARY 1156 (10th ed. 2017).

also emphasized that the challenge/re-challenge[37] framework supported the medical theory of the timing of Petitioner's condition's onset, because the more noticeable symptoms of this disease, like bleeding gums and nosebleeds, began only after Petitioner received the third dose of the HPV vaccine. 6/6/2017 TR at 142–43. Therefore, Dr. Shoenfeld "ha[d] no problem with the [theory that onset could take] six months nor with the four months and definitely not with the shorter periods." 6/6/2017 TR at 143.

Dr. Shoenfeld also explained that his initial diagnosis of Petitioner included SLE, as well as ITP and antiphospholipid antibodies. 6/6/2017 TR at 143. But, in later reports and at the time of his testimony, Dr. Shoenfeld became "confident" that Petitioner did not have lupus, because she had "none of the organ involvement[ ]" expected. 6/6/2017 TR at 144. Dr. Shoenfeld also was confident that Petitioner did not have antiphospholipid syndrome, but he could not "guarantee that she [would] not develop" either antiphospholipid syndrome or SLE in the future. 6/6/2017 TR at 145. Therefore, he concluded that Petitioner "definitely" had ITP, and that there was no question in his mind that a molecular mimicry process between the HPV vaccine and Petitioner's platelets caused Petitioner to have ITP. 6/6/2017 TR at 145, 147–48.

Dr. Shoenfeld added that Dr. Darja Kanduc of the University of Bari, Italy, published a case study of Petitioner in a peer-reviewed journal, in part in order to "get the approval of . . . world[-]known [experts] in the field" as to his theory of Petitioner's condition. 6/6/2017 TR at 147–49.

3. The Government's Expert—Dr. Rose.

Dr. Carlos Rose testified as an expert for the Government, is board-certified in General Pediatrics and Pediatric Rheumatology, and works at the Nemours Foundation at duPont Children's Hospital. 6/7/2017 TR at 176–77. As the Head of his Division, Dr. Rose has administrative responsibilities, runs a research program on a genetic disease, holds six half-day clinics a week, and is Chair of the Institutional Review Board. 6/7/2017 TR at 177–78. Dr. Rose testified that he has experience diagnosing and treating juvenile patients with lupus and sees juveniles with chronic or persistent ITP. 6/7/2017 TR at 178–79. Dr. Rose was admitted to testify as an expert in the field of pediatric rheumatology. 6/7/2017 TR at 179.

[37] In the medical context, "challenge" refers to "the administration of . . . a chemical or antigen in order to assess for a response." DORLAND'S at 336. "Challenge/re-challenge" is "a paradigm for exploring whether one substance caused an adverse reaction. 'Under this model, an individual who has had an adverse reaction to the initial vaccine dose (the challenge event) suffers a worsening of symptoms after a second or third injection (the re-challenge event)." *Viscontini v. Sec'y of Health & Human Servs.*, No. 98-619V, 2011 WL 5842577, at *22 (Fed. Cl. Spec. Mstr. Oct. 21, 2011) (quoting *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 603 (Fed. Cl. 2010), *mot. for review denied*, 103 Fed. Cl. 600 (Fed. Cl. 2012)); *see also Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1322 (Fed. Cir. 2006) ("A re[-]challenge event occurs when a patient who had an adverse reaction to a vaccine suffers worsened symptoms after an additional injection of the vaccine.").

Dr. Rose testified that, based on the two reports he provided as an expert for the Government, Petitioner was properly diagnosed with SLE. 6/7/2017 TR at 179–80. Lupus appears on a "spectrum of severity," where some patients may have "mild rashes, mild arthritis, and . . . general symptoms," but others experience "a stroke or a coma or psychiatric presentations," with very little inflammation or other typical symptoms of lupus. 6/7/2017 TR at 180–81. Other patients evidence "hematologic lupus," that can be confirmed only by "hematology abnormalities" and may "never evolv[e] to full-blown lupus." 6/7/2017 TR at 181–82. For this reason, Dr. Rose emphasized the importance of clinical monitoring, so that even "subclinical manifestations . . . that [the patients] may not even know they have," like proteinuria,[38] can be monitored and tested. 6/7/2017 TR at 182.

Dr. Rose testified, however, that there is no consensus about what causes SLE. 6/7/2017 TR at 182. "[M]ost authors believe" that SLE is "an idiopathic[39] disease," because it is associated with "a combination of genetic factors," rather than "any specific or unquestionable mechanism." 6/7/2017 TR at 182. "[E]nvironmental factors . . . may or may not trigger" SLE, but certain genetic traits are required. 6/7/2017 TR at 182–84.

Dr. Rose summarized Petitioner's medical history, as presenting EBV in her blood-test results, as well as the antinuclear antibody, low positive anti-double stranded DNA, and negative direct Coombs test. 6/7/2017 TR at 190. Petitioner also had a positive indirect Coombs test that evidenced a "positive triple-hit antibody for the antiphospholipid syndrome, including . . . anticardiolipin antibodies, lupus anticoagulant and anti beta-2 glycoprotein antibodies." 6/7/2017 TR at 191. Dr. Rose also explained that the positive test for lupus anticoagulant was significant, because lupus anticoagulant is the "most indicative [factor] of the risk of thrombosis" and is found in up to forty percent of patients with lupus and up to fifty percent of pediatric lupus patients. 6/7/2017 TR at 195.

Dr. Rose added that the 1997 edition of the ACR Diagnostic Criteria, that Petitioner's treating physicians used to evaluate Petitioner for lupus, was "never validated;" instead, he would have relied on the 2012 SLICC criteria. 6/7/2017 TR at 188. He found that Petitioner met four of the eleven SLICC criteria: thrombocytopenia; positive antinuclear antibodies; positive double-stranded DNA; and positive anticardiolipin laboratory tests. 6/7/2017 TR at 191–92. He also explained that he would not diagnose Petitioner with ITP, because Petitioner had additional symptoms and Dr. Rose understood ITP to require only thrombocytopenia. 6/7/2017 TR at 199–200.

As for the medical literature relied on by Dr. Shoenfeld, Dr. Rose explained that the case control and cohort studies offered by the Government used more reliable methodologies than the case studies supplied by Petitioner. 6/7/2017 TR at 202–12. Because SLE existed in humans "for many, many years before any vaccine was ever invented," studies of the causal mechanism between the HPV vaccine and lupus need to be carefully controlled to compare the number of

[38] "Proteinuria" is "excessive serum proteins in the urine, such as in renal disease, after strenuous exercise, and with dehydration." DORLAND'S at 1535.

[39] "Idiopathic" describes a condition "of unknown origin or spontaneous origin." DORLAND'S at 912.

patients where lupus is triggered by a vaccine to the number of patients who would have lupus even without a vaccine. 6/7/2017 TR at 213–15. Dr. Rose also expressed his opinion that EBV can trigger ITP and that Petitioner may have had mononucleosis without being aware of it. 6/7/2017 TR at 216–18.

As for the "reasonableness" of Dr. Shoenfeld's theory that molecular mimicry caused Petitioner's ITP, Dr. Rose stated that molecular mimicry is a "well-established immunopathogenesis theory . . . known since the time of rheumatic fever," but he found little evidence in Petitioner's case and concluded that Dr. Shoenfeld's theory required "a major leap of faith." 6/7/2017 TR at 218–20.

After examining a photograph of Petitioner's May 2012 hematoma, Dr. Rose also testified that the photograph did not show evidence of either lupus or ITP. 6/7/2017 TR at 220–21. In addition, the duration of a hematoma has no relationship to platelet counts, but instead affects the "depth of the bleeding" that causes a hematoma. 6/7/2017 TR at 220–21.

In conclusion, based on his review of Petitioner's medical records, Dr. Rose testified that there was "no evidence" that the HPV vaccine caused Petitioner's condition. 6/7/2017 TR at 222.

4. The Government's Expert—Dr. Forsthuber.

The Government's second Expert was Dr. Thomas Forsthuber, a Professor of Immunology and an Endowed Chair of Biotechnology at the University of Texas at San Antonio, and an Adjunct Professor of Pathology, Microbiology, and Immunology at the University of Texas Health Sciences Center. 6/7/2017 TR at 271. He received a M.D. degree and a Doctorate in Medicine from University Tübingen, has "studied autoimmune diseases for a very long time," and runs a laboratory that conducts research on autoimmunity. 6/7/2017 TR at 272; ECF No. 29-2 at 2 (Curriculum Vitae). Dr. Forsthuber is also a reviewer and editor of medical journals concerning immunology and autoimmunity and has published approximately eighty papers and several book chapters on immunology. 6/7/2017 TR at 272. In addition, Dr. Forsthuber is board-certified in Anatomical and Clinical Pathology. 6/7/2017 TR at 272. Dr. Forsthuber was admitted to testify at the entitlement hearing as an expert in the field of immunology. 6/7/2017 TR at 273.

Dr. Forsthuber testified that, after reviewing all the evidence and attending the first day of the hearing, he concluded that the HPV vaccine was not associated with Petitioner's condition. 6/7/2017 TR at 274. It was "not more likely than not" that the HPV vaccine caused Petitioner to develop either ITP or lupus. 6/7/2017 TR at 274–75.

Dr. Forsthuber added that Dr. Shoenfeld's molecular mimicry theory was not supported by "reliable, persuasive evidence." 6/7/2017 TR at 275–82. In fact, one of Dr. Shoenfeld's co-authors, Dr. Kanduc, concluded, after conducting research into molecular mimicry, that: "'the massive viral to human peptide overlapping calls into question the possibility of a direct causal association between virus-host sharing of amino acid sequences and incitement to autoimmune reactions,'" or the "concept of molecular mimicry." 6/7/2017 TR at 282 (quoting Darja Kanduc et al., *Massive Peptide Sharing Between Viral and Human Proteomes*, Peptides, Oct. 2008, at 1).[40]

[40] For this portion of his testimony, Dr. Forsthuber appeared to be quoting from an article by Dr. Darja Kanduc, "Quantifying the Possible Cross-Reactivity Risk of an HPV16 Vaccine,"

After discussing several other medical articles, Dr. Forsthuber concluded that "the field in general has failed" to show that the theory of molecular mimicry is reliable by demonstrating a predictable causal connection between the introduction of an infectious organism and the onset of an autoimmune disorder. 6/7/2017 TR at 283–95.

Dr. Forsthuber also called into question the timing of Petitioner's symptoms' onset under the challenge/re-challenge framework, because "after the third challenge" of the third HPV vaccine administration, he "would have expected a faster response" than what Petitioner experienced. 6/7/2017 TR at 305–06. Therefore, Dr. Forsthuber concluded that it was "very unlikely" Petitioner's HPV vaccine could have caused the production of peptides that would induce autoimmunity. 6/7/2017 TR at 308.

II. DISCUSSION.

A. Jurisdiction.

The United States Court of Federal Claims has jurisdiction to review the decision of a Special Master in a vaccine-related injury case, pursuant to 42 U.S.C. § 300aa-12(e)(2) and Vaccine Rule 23(a). After reviewing the Special Master's decision, the court may

> (A) uphold the findings of fact and conclusions of law of the Special Master and sustain the Special Master's decision,
>
> (B) set aside any findings of fact or conclusion of law of the Special Master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the Special Master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2); *accord* Vaccine Rule 27.

B. Standing.

A petition under the Vaccine Program may be filed by "any person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died as the result of the administration of a vaccine" covered by the Vaccine Program. 42 U.S.C. § 300aa-11(b)(1)(A). A petition may not be filed if a petitioner has previously filed a "pending [ ] civil action for damages for [the same] vaccine-related injury or death." 42 U.S.C. § 300aa-11(a)(5)(B).

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submitted as Pet. Ex. 39. In fact, the quoted language appears in a different article authored by Dr. Kanduc, cited here.

In this case, Petitioner has standing to seek an adjudication of the March 10, 2015 Petition, because it was filed by her mother, when Petitioner was a minor, and it alleged that Petitioner suffered from a vaccine-related injury. 3/10/2015 Pet. at 1. The March 10, 2015 Petition also alleged, and the Government does not dispute, that Petitioner has not initiated any civil action for damages, based on her allegations of a vaccine-related injury. 3/10/2015 Pet. at 8.

C. Standard Of Review.

Congress authorized the United States Court of Federal Claims with jurisdiction to adjudicate entitlement decisions of Special Masters under the Vaccine Act. *See* 42 U.S.C. § 300aa-12(e)(2)(B); *see also Saunders v. Sec'y of Health & Human Servs.*, 25 F.3d 1031, 1033 (Fed. Cir. 2004) ("Fact findings are reviewed by [the United States Court of Appeals for the Federal Circuit], as by the [United States Court of Federal] Claims [ ] judge, under the arbitrary and capricious standard; legal questions under the 'not in accordance with law' standard; and discretionary rulings under the abuse of discretion standard." (quoting *Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992))); *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1527 (Fed. Cir. 1991) ("The 'not in accordance with the law' aspect of the standard of review is . . . involved . . . [where there is] dispute over statutory construction or other legal issues.").

D. The Elements And Burden Of Proof In Vaccine Act Cases.

The Vaccine Act provides that a petitioner may receive compensation and other relief, if an injury can be established, either by causation-in-law or causation-in-fact. Causation-in-law is established if one of the vaccines listed in the Vaccine Injury Table at 42 U.S.C. § 300aa-14(a) ("Vaccine Injury Table") was administered and the "first symptom or manifestation of onset" of specific adverse medical conditions associated with the use of each vaccine occurred within a time period specified in the Vaccine Injury Table.[41] *See* 42 U.S.C. § 300aa-14(a); 42 C.F.R. § 100.3(a) (2017). Congress required that the Vaccine Injury Table is to be read and interpreted by reference to "qualifications and aids to interpretation," that define the key terms used therein. *See* 42 U.S.C. § 300aa-14(b).

The Vaccine Act also affords a petitioner an opportunity to receive compensation, even if the time period for the first symptom or manifestation of a specified injury is not listed in the Vaccine Injury Table, *i.e.*, for an "off-Table" vaccine injury. *See* 42 U.S.C. §§

[41] The relevant part of the Vaccine Injury Table in this case provides:

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
XVI. Human papillomavirus (HPV) vaccines.	A. Anaphylaxis.....	≤ 4 hours.
	B. Shoulder Injury Related to Vaccine Administration.	≤ 48 hours.
	C. Vasovagal Syncope.....	≤ 1 hour.

42 C.F.R. § 100.3(a).

300aa-11(c)(1)(C)(ii), 300aa-13. In such cases, however, the petitioner must establish causation-in-fact, by offering sufficient facts to establish each element of a vaccine injury claim and must meet the burden of proof as to each element by a "preponderance of the evidence." *See* 42 U.S.C § 300aa-13.

In *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005) ("*Althen*"), the United States Court of Appeals for the Federal Circuit established a three-part test for determining causation-in-fact in off-Table vaccine injury cases. *Id.* at 1278–82. Under this three-part test, a petitioner is required to show:

> by preponderant evidence that the vaccination brought about [the] injury by providing:
> (1) a medical theory causally connecting the vaccination and the injury;
> (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and
> (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. at 1278. In *Capizzano v. Secretary of Health & Human Services*, 440 F.3d 1317 (Fed. Cir. 2006), the United States Court of Appeals for the Federal Circuit re-affirmed the three-part test established in *Althen*. *Id.* at 1324; *see also Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2012) (applying the *Althen* standard to a Vaccine Program petition).

If a petitioner establishes causation-in-fact, then the burden of proof shifts to the Government to establish that a factor unrelated to the vaccine was the cause of a petitioner's injury. *See* 42 U.S.C. § 300aa-13(a)(1)(B); *see also Althen*, 418 F.3d at 1278 ("If [the petitioner] satisfies this burden, [the petitioner] is entitled to recover [damages,] unless [the Government] shows, by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.") (internal quotation marks omitted).

E. The Special Master's February 5, 2018 Decision.

Because the March 10, 2015 Petition alleged an off-Table Injury, Petitioner was required to "demonstrate that the vaccine was 'not only the but-for cause of the injury but also a substantial factor in bringing about the injury.'" 2/5/2018 Dec. at 16 (quoting *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010) (punctuation omitted)). A petition making such a showing must be "supported by either medical records or by the opinion of a competent physician," and must "satisfy all three of the elements established by the Federal Circuit in *Althen*." 2/5/2018 Dec. at 16 (citing Vaccine Rule 13(a)(1); *Althen*, 418 F.3d at 1278). In this case, the Special Master determined that Petitioner did not establish entitlement to compensation, because she failed to meet her burden to show that "onset of her ITP occurred in a medically acceptable timeframe, or that the vaccine more likely than not caused her ITP." 2/5/2018 Dec. at 2.

First, the Special Master found that Petitioner did not met her burden under the third element of *Althen*, because she proffered evidence that the HPV vaccine caused chronic ITP, instead of an acute condition, that rendered the onset date "difficult" to determine, but that "evidence of an initial physical manifestation of ITP is likely the most reliable proof of onset available." 2/5/2018 Dec. at 21.

Second, the Special Master determined that Petitioner's medical evidence, as to the timing of her ITP's initial physical manifestation, was inconsistent with testimony proffered by Petitioner's mother and Petitioner at the entitlement hearing. 2/15/18 Dec. at 21. Statements made to medical providers, as evidenced by Petitioner's medical records, indicate that Petitioner and her mother initially believed onset of Petitioner's condition occurred in July 2013, *i.e.*, six months after Petitioner received the first dose of HPV vaccine. 2/5/2018 Dec. at 21–22. At the entitlement hearing, however, Petitioner testified that onset was in March 2013, when she first noticed that she bruised more easily. 2/5/2018 Dec. at 22. The Special Master found the March 2013 onset date was less credible than the July 2013 onset date for two reasons: (1) the March 2013 date Petitioner proffered at the hearing was "not corroborated by any medical records;" and (2) if Petitioner's condition was noticeable in March 2013, Petitioner and her mother waited nine months after onset to seek treatment, a "far longer, less credible delay, especially if the purported March symptoms were followed by the July 2013 incident, and then continued for the rest of the year." 2/5/2018 Dec. at 22. Therefore, the Special Master found that the evidence supported a conclusion that "the outward symptoms of [Petitioner's] ITP were observed no earlier than July 2013." 2/5/2018 Dec. at 22.

Having determined that the onset of Petitioner's condition manifested in July 2013, the Special Master next determined that the six-month delay between Petitioner's last dose of the HPV vaccine and the July 2013 onset date was not a medically reasonable timeframe for onset of chronic ITP. 2/5/2018 Dec. at 22. Although, Dr. Shoenfeld testified that "an autoimmune reaction of this type could take many weeks, months, or even years to develop," based on "literature that reported long onset between vaccine and injury," that literature did not address "injuries relevant to this case." 2/5/2018 Dec. at 22 (citing ECF No. 24-3 (abstract of an article about Guillain-Barré syndrome[42]); ECF No. 24-4 (article about macrophagic myofasciitis[43])). Dr. Shoenfeld also testified that, in other Vaccine Program cases where he testified, he "put forward the particularly unpersuasive contention that virtually *any* timeframe post-vaccination is medically acceptable for onset of an autoimmune condition." 2/5/2018 Dec. at 23 n.20 (italics in original).

Therefore, the Special Master credited the testimony of the Government's expert, Dr. Forsthuber, who "allowed for a timeframe of up to 28 days after vaccination for onset of an autoimmune condition like ITP," although the condition could take longer than that to manifest, but "the further past four weeks, the more unlikely that the vaccine could be deemed causal." 2/5/2018 Dec. at 23. The Special Master also relied on the findings of prior Vaccine Program

[42] "Guillain-Barré syndrome" is "rapidly progressive ascending motor neuron paralysis of unknown etiology, frequently seen after an enteric or respiratory infection. An autoimmune mechanism following viral infection has been postulated. It begins with paresthesias of the feet, followed by flaccid paralysis of the entire lower limbs, ascending to the trunk, upper limbs, and face; other characteristics include slight fever, bulbar palsy, absent or lessened tendon reflexes, and increased protein in the cerebrospinal fluid without a corresponding increase in cells." DORLAND'S at 1832.

[43] A "macrophage" is "any of the many forms of mononuclear phagocytes found in tissues." DORLAND'S at 1093. "Myofasciitis" is the "inflammation of a muscle and its fascia, particularly of the fascial insertion of muscle to bone." *Id.* at 1223.

cases, that found an autoimmune condition could take up to six weeks to manifest. 2/5/2018 Dec. at 23. Therefore, the Special Master concluded that "[a] timeframe of four to six weeks post-vaccination has far more support," than the theory offered by Dr. Shoenfeld, who "did not persuasively establish otherwise;" as such, Petitioner failed to meet her burden of proof under the third element of *Althen.* 2/5/2018 Dec. at 23.

Next, the Special Master found Petitioner failed to show, by a preponderance of the evidence, the HPV vaccine was the "but-for" cause of her condition. 2/5/2018 Dec. at 23. Instead, the Special Master found that the record supported the conclusion that Petitioner's condition was ITP, not lupus. 2/5/2018 Dec. at 23. As such, Dr. Shoenfeld "credibly explain[ed] how the record did not corroborate" the contrary testimony by the Government's expert, Dr. Rose. 2/5/2018 Dec. at 24. The Special Master also found that, although Petitioner's ITP manifested after she received the vaccine, Petitioner did not "provide[ ] a compelling narrative" establishing a causal relationship between the vaccine and her condition. 2/5/2018 Dec. at 24. In particular, "[n]o treaters ever proposed a relationship between the HPV vaccine and Petitioner's ITP." 2/5/2018 Dec. at 24. The record evidence also was "suggestive of alternative causes," such as the EBV titers in Petitioner's first blood work and the "'red flag' blood testing results obtained by Dr. Shah that supported a lupus diagnosis." 2/5/2018 Dec. at 24. These alternative explanations, albeit "admittedly-inconclusive," also "diminish[ed] the strength of Petitioner's evidentiary showing (even if this evidence [did] not itself stand as preponderant proof of an alternative cause)." 2/5/2018 Dec. at 24.

The Special Master also cited the "analytic concept of challenge/re[-]challenge," as "underscor[ing] the deficiencies" of Petitioner's *Althen* element two analysis. 2/5/2018 Dec. at 24. Based on that theory, Petitioner's immunological reaction to the HPV vaccine should have worsened with each successive dose. 2/5/2018 Dec. at 24. But, Petitioner alleged a reaction four months after her first vaccine dose and four months after her third dose; no reaction followed her second dose. 2/5/2018 Dec. at 24. This led the Special Master to conclude that "[wh]ere challenge/re-challenge [was] occurring, each reaction should have been *closer* in time to the next dose." 2/5/2018 Dec. at 24 (italics in original). Petitioner's failure to make such a showing, by a preponderance of the evidence, undermined the theory that the HPV vaccination was the but-for cause of Petitioner's ITP. 2/5/2018 Dec. at 24.

Nevertheless, the Special Master found that Petitioner met her burden under the first element of *Althen* by establishing that the HPV vaccine can cause autoimmune disorders like ITP. 2/5/2018 Dec. at 24. Although the Government supplied "some persuasive, robust" epidemiologic evidence to the contrary and Dr. Forsthuber's testimony "raised reasonable questions about the plausibility" of Petitioner's theory, it was "fairly well established in other Program decisions that ITP . . . has been credibly associated with vaccination," including the HPV vaccine. 2/5/2018 Dec. at 24–25. For that reason, the Special Master credited Dr. Shoenfeld's testimony as "persuasively establish[ing] in this case that the HPV vaccine could cause ITP." 2/5/2018 Dec. at 25. But, because Petitioner did not meet her burden to establish the other two elements of the *Althen* analysis, the Special Master concluded that Petitioner was not entitled to an entitlement damages award and dismissed the March 10, 2015 Petition. 2/5/2018 Dec. at 25.

F. Petitioner's March 7, 2018 Motion For Review.

1. Petitioner's Arguments.

Petitioner argues that the February 5, 2018 Decision Denying Entitlement is "arbitrary, capricious, and contrary to law," and reflects "multiple legal errors that require appellate intervention." Pet. Mot. at 1–2. First, the Special Master imposed "too high of a burden" of proof on Petitioner to establish a causal relationship between the HPV vaccine and Petitioner's autoimmune condition: "[e]ven if the case on causation can be characterized as a 'close call,' the mandate is to award compensation." Pet. Mem. at 13–14 (citing *Harris v. Sec'y of Health & Human Servs.*, 102 Fed. Cl. 282, 303 (Fed. Cl. 2011) ("If the evidence is seen in equipoise, then the government has failed in its burden of persuasion and compensation must be awarded . . . especially in view of . . . the generosity of the Vaccine Act.") (internal quotation marks omitted).

Second, the Special Master erred in finding that Petitioner did not meet the burden of proof under the third element of *Althen*. Pet. Mem. at 14. For example, the Special Master found that the onset of Petitioner's condition first was observed in July 2013; but, Petitioner and her mother testified that they had observed Petitioner's symptoms in March 2013. Pet. Mem. at 14. Even so, Petitioner argues that "Dr. Shoenfeld's testimony encompasses both dates as temporally appropriate." Pet. Mem. at 14. Dr. Shoenfeld also testified that ITP's onset "'may take months and sometimes it may take years;'" in contrast, the Government's expert, Dr. Forsthuber, agreed that a six-month onset was "possible." Pet. Mem. at 15 (citing 6/6/2017 TR at 86; 6/7/2017 TR at 304, 324, 326). The Special Master, however, did not explicitly find that Dr. Shoenfeld was not credible and found that the onset of ITP "can vary from weeks to years." 2/5/2018 Dec. at 14. Also, Petitioner concluded that the Special Master "agreed with Petitioner['s] temporal theory" and his decision that Petitioner did not meet her burden of proof, under the third element of *Althen*, was an erroneous substitution of the Special Master's judgment and was not supported in light of Petitioner's expert evidence. Pet. Mem. at 15, 16, 17 (quoting 2/5/2018 Dec. at 14).

Third, Petitioner contends that she met her burden under the second element of *Althen* by presenting a "logical" sequence of cause and effect, *i.e.*, Petitioner had no "previous history of coagulation abnormalities nor autoimmune disease," prior to her first HPV vaccine, but "developed additional, significant bruising and ultimately was found to have abnormally low platelets" after the third HPV vaccine. Pet. Mem. at 18. In addition, Petitioner objected to the Special Master's reliance on the fact that "[n]o treaters ever proposed a relationship between the HPV vaccine and Petitioner's ITP" to deny an award of compensation. Pet. Mem. at 18 (quoting 2/5/2018 Dec. at 24). Not only is such a nexus not "required for compensation to be awarded," but the Special Master's belief that a nexus was missing is erroneous, because Petitioner's treating physician provided her with a "vaccine exemption," based on "past vaccine reactions." Pet. Mem. at 19 (citing ECF No. 45-1). Therefore, Petitioner concludes that an exemption must be "probative evidence" of vaccine causation. Pet. Mem. at 19 (citing *Kelley v. Sec'y of Health & Human Servs.*, 68 Fed. Cl. 84, 98, 100 (2005) (determining that the petitioner's treating physicians' reluctance to authorize the petitioner with further tetanus vaccinations was "robust" medical evidence of vaccine causation); *see also Andreu v. Sec'y of Health & Human Servs.*, No. 98-817V, 2008 WL 2009746,

at *6[44] (Fed. Cl. Mar. 3, 2008) (interpreting *Kelley* to determine that a treating physician's "no-more-vaccine" instruction could be construed as supporting vaccine causation)). Therefore, the Special Master's "fail[ure] to consider this evidence" renders the February 5, 2018 Decision arbitrary. Pet. Mem at 19.

Finally, Petitioner argues that, because she met all three elements of *Althen*, the burden of proof shifted to the Government to establish an "alternative factor" that caused Petitioner's injury, but the Government failed to do so. Pet. Mem. at 19 (citing *Porter*, 663 F.3d at 1249[45] ("Once causation is established, the petitioner is entitled to compensation[,] unless the government can show by a preponderance of the evidence that the injury is due to factors unrelated to the vaccine, i.e., an alternative cause." (citation omitted); *see also Heinzelman v. Sec'y of Health & Human Servs.*, No. 07-01V, 2008 WL 5479123, at *19[46] (Fed. Cl. 2008) (requiring the Government to demonstrate alternative causation by the same standards of proof that apply to a petitioner's primary theory of causation); *Porter*, 663 F.3d at 1249[47] ("Once causation is established, the petitioner is entitled to compensation[,] unless the government can show by a preponderance of the evidence that the injury is due to factors unrelated to the vaccine, i.e., an alternative cause." (citation omitted))). In this case, the Government proffered an "extremely questionable alternative explanation" that Petitioner was exposed to her babysitter's mononucleosis, a theory that even the Special Master found was supported by "'admittedly-inconclusive' evidence." Pet. Mem. at 20 (quoting 2/5/2018 Dec. at 24). In addition, the Government failed to provide a "known alternative factor" to explain Petitioner's condition, because: (1) Petitioner's positive EBV titer was the only evidence to support the theory that mononucleosis caused Petitioner's condition; (2) neither expert found the EBV titer was probative as to whether or when Petitioner had mononucleosis; and (3) "the Special Master acknowledged that [Petitioner] does not have lupus." Pet. Mem. at 20.

In sum, Petitioner contends that she met her burden under *Althen* by establishing that the HPV vaccine caused her to experience ITP and the Government failed to establish an alternative explanation. Pet. Mem. at 20. As such, the Special Master's February 5, 2018 Decision that Petitioner was not entitled to compensation for her injury was contrary to law. Pet. Mem. at 20.

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[44] Petitioner did not supply a pinpoint citation for this opinion. The court supplies the correct page number.

[45] Petitioner cited to an unofficial commercial reporter, but also did not supply a pinpoint citation for this opinion. The court cites to the relevant portion in the Federal Reporter and supplies the correct page number.

[46] Petitioner did not supply a pinpoint citation for this opinion. The court supplies the correct page number.

[47] Petitioner cited to an unofficial commercial reporter, but also did not supply a pinpoint citation for this opinion. The court cites to the relevant portion in the Federal Reporter and supplies the correct page number.

2. The Government's Response.

The Government responds that the Special Master applied the correct standards in finding that Petitioner did not met her burden under *Althen*. Gov't Resp. at 11. First, the Special Master found that Petitioner met her burden under the first element of *Althen*, by showing that the HPV vaccine "could cause ITP," based "largely on other Vaccine Program cases" that accepted the theory of molecular mimicry advanced by Dr. Shoenfeld, but found that a petitioner nevertheless could fail to meet her burden under the second and third elements of *Althen*. Gov't Resp. at 12. Instead, Petitioner failed to show, by preponderant evidence, that Petitioner's theory of the vaccine causation "fits the timing of onset of the alleged vaccine injury in a medically-appropriate manner," as required by *de Bazan v. Secretary of Health and Human Services*, 539 F.3d 1347 (Fed. Cir. 2008). Gov't Resp. at 12 (citing *de Bazan*, 539 F.3d at 1352 ("[T]he proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact[.]")). In addition, the Government argues that the Special Master's determination that Petitioner failed to establish "a medically acceptable onset of symptoms," as required by the third element of *Althen*, has "ample support" in the record. Gov't Resp. at 12. The Special Master correctly found the medical documentary evidence in favor of a July 2013 onset date more credible than the witness testimony of Petitioner and her mother in favor of a March 2013 onset date, in light of "the evidence as a whole." Gov't Resp. at 12–14 (citing 2/5/2018 Dec. at 21–22).

After determining that July 2013 was the more credible onset date, the Special Master weighed the experts' testimony as to "whether an onset of ITP six months after vaccination fits with [P]etitioner's molecular mimicry theory." Gov't Resp. at 14. The Special Master's finding not to credit Dr. Shoenfeld's theory of molecular mimicry was supported by Dr. Shoenfeld's having "similarly and unpersuasively testified in other Vaccine Program cases" that a wide variety of onset times can support the existence of an autoimmune condition. Gov't Resp. at 14. Instead, the Special Master found to be credible Dr. Forsthuber's testimony that an onset timeframe of up to twenty-eight days would support a causal relationship, and that beyond four weeks it became less likely that ITP was causally related to the vaccine. Gov't Resp. at 15. Therefore, the Special Master found that "a timeframe of four to six weeks post-vaccination" was best supported by the record and determined that Petitioner did not satisfy her burden under the third element of *Althen*. Gov't Resp. at 15–16 (citing 2/5/2018 Dec. at 23).

In addition, the Government argues that the Special Master's finding that Petitioner did not "'provided a compelling narrative'" to establish "a 'logical sequence of cause and effect,'" as required by the second element of *Althen*, was supported by the record. Gov't Resp. at 16 (quoting 2/5/2018 Dec. at 24). That finding was supported by the absence of record evidence that any of Petitioner's treating physicians considered the HPV vaccine as a cause of ITP, as well as by Dr. Forsthuber's testimony that the timing of Petitioner's symptoms did not conform with the timeline that he would expect under the challenge/re-challenge framework. Gov't Resp. at 16–17 (citing 2/5/2018 Dec. at 24).

As such, the Special Master correctly "applied the controlling law on evaluating medical records versus contrary fact testimony," considered the relevant evidence, and gave sufficient reasons for his finding that Petitioner did not meet her burden to establish entitlement to compensation. Gov't Resp. at 18.

3. Petitioner's Reply.

Petitioner replies that neither the Special Master nor the Government acknowledged that Petitioner's treating physician issued a vaccine exemption for Petitioner, because of "past reactions." Pet. Reply at 1. Prior decisions of the United States Court of Federal Claims have found that such exemptions have been "construed as probative evidence." Pet. Reply at 1–2 (citing *Kelley*, 68 Fed. Cl. at 98, 100; *Andreu*, 2008 WL 2009746, at *6[48]). The Special Master's failure to consider the vaccine exemption in this case renders his decision arbitrary. Pet. Reply at 2.

Petitioner also reiterates that Petitioner and her mother gave "clear testimony" that Petitioner showed symptoms of ITP in March 2013. Pet. Reply at 2. Because the Special Master never made explicit a finding that Petitioner or her mother were not credible witnesses, the Special Master erred in discounting their testimony in finding that the onset of Petitioner's ITP was in July 2013. Pet. Reply at 2–3. Petitioner also adds that, because the Special Master found the March 2013 onset not credible and the July 2013 onset to be too late to be causally linked to the HPV vaccine, "either way, Petitioner loses." Pet. Reply at 4. But, "[w]hether the onset is March or July of 2013, Dr. Shoenfeld's theory still encompasses both dates," and the Special Master provided no rationale for not crediting that theory. Pet. Reply at 5.

Finally, Petitioner reiterates that the Special Master found that the first element of *Althen* was established by a preponderance of the evidence. Pet. Reply at 5.

4. The Court's Resolution.

Petitioner's primary contention in seeking review is that the Special Master imposed "too high a burden" as to the second and third elements of *Althen* and, in doing so, erred in finding that Petitioner's expert's theory of vaccine causation was not credible. Pet. Mem. at 12, 14–19.

Petitioner does not dispute the Special Master's finding that the onset of her ITP was in July 2013, but argues that Dr. Shoenfeld's theory of causation should have been found medically plausible, even for that later onset date. Pet. Mem. at 14, 15. This is so, because Dr. Forsthuber conceded that a six-month onset window was possible, but the Special Master found that "[t]he range for onset can vary" and ITP's onset can be "insidious." Pet. Mem. at 17 (citing 6/7/2017 TR at 304; 2/5/2018 Dec. at 14). Therefore, Petitioner challenges the Special Master's finding that Dr. Shoenfeld's theory of Petitioner's condition's onset was not credible. Pet. Mem. at 17–18.

The Special Master's credibility determinations are "fact-based conclusions" entitled to "great deference," and will not be disturbed on review, unless found to be arbitrary and capricious. *See Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010); *see*

[48] Petitioner did not provide a pinpoint citation for this authority. The court construes Petitioner to refer to the location of the pinpoint citation supplied here.

also Munn, 970 F.2d at 870 ("[T]he only time the Claims Court can make its own findings of fact is when that court, as a matter of law, has concluded that the special master was 'arbitrary and capricious[.]'"). "It is not [the court's] role to 'second guess the Special Master's fact-intensive conclusions[,] particularly in cases in which the medical evidence of causation is in dispute.'" *Porter*, 663 F.3d at 1249 (quoting *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010)).

Petitioner overstates Dr. Forsthuber's agreement with Dr. Shoenfeld's proposition that the onset of ITP's can vary widely. *Compare* Pet. Mem. at 15 ("Dr. Forsthuber, Respondent's expert, testified that the six-month interval was possible."), *with* 6/7/2017 TR at 303–04 (Dr. Forsthuber relying on "animal models . . . [and] post-vaccine observations" to conclude that "a six-month interval is not completely impossible but just decreases the likelihood of [vaccine causation] being possible."). Likewise, Petitioner's argument that the February 5, 2018 Decision "agreed with Petitioner['s] temporal theory" does not accurately reflect that the Special Master found in general that ITP could take "weeks to years" to manifest, but also made an explicit finding that the expert testimony, in this case, was that vaccine-induced ITP was more likely to manifest within four to six weeks of vaccination. 2/5/2018 Dec. at 14, 22–23 (citing 6/6/2017 TR at 86, 139–41; ECF No. 24-4; ECF No. 24-5; 6/7/2017 TR at 303–04). This finding is also consistent with other Vaccine Program decisions finding that ITP plausibly could be attributed to vaccination, if it developed within six weeks of vaccination. 2/5/2018 Dec. at 23.

It is well established that a Special Master is entitled to determine the weight afforded to testimony and medical theories. *See, e.g.*, *Moberly*, 592 F.3d at 1326 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."). Because the Special Master relied on the testimony offered by Dr. Forsthuber and "well-reasoned decisions of [the Vaccine Program] involving ITP," the record taken as a whole supports the Special Master's determination that the onset of Petitioner's ITP after six months was not plausibly causally related to the HPV vaccine. 2/5/2018 Dec. at 23; *see also Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1358 (Fed. Cir. 2010) (holding that because Section 300aa-13 requires that a special master's findings be "based 'on the record as a whole,'" a special master can consider evidence that undermines the petitioner's argument while evaluating the *prima facie* case) (quoting 42 U.S.C. § 300aa-13(a)(1)).

Petitioner adds that the Special Master's factual findings created a situation where "Petitioner loses" no matter what. Pet. Reply at 4. But, the Special Master found that the onset of Petitioner's ITP was in July 2013, rather than in March 2013, based on the testimony of Petitioner and her mother—therefore, Petitioner's ITP manifested too late to be caused by the HPV vaccination. Pet. Reply at 3. For the first time in the Reply, Petitioner argues that the July 2013 onset determination was made in error and that a finding of onset in March 2013 would render Petitioner's theory credible under *Althen*'s third element. Pet. Reply at 4–5. *Cf.* Pet. Mem. at 18 ("Whether onset was in March or July of 2013 makes no difference."). The Reply insists that "Dr. Shoenfeld's theory still encompasses both dates," and argues that, even if the Special Master's finding of a July 2013 onset date is upheld, Petitioner has met the burden under the third element of *Althen*. Pet. Reply at 4–5.

Again, as a matter of law, the court's review does not "distinguish between cases in which onset is too soon and cases in which onset is too late; in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *de Bazan*, 539 F.3d at 1352. In this case, the Special Master found that the testimony of Petitioner and her mother less credible than the contemporaneous medical records that established a July 2013 onset date. 2/5/2018 Dec. at 21–22. In addition, the Special Master reviewed all the medical literature filed by the parties and heard the experts' testimony before concluding that Dr. Shoenfeld's theory was not supported by evidence. 2/5/2018 Dec. at 22–23; *see also Porter*, 663 F.3d at 1253–54 (holding that the "thorough and careful evaluation of all the evidence including records, tests, reports, and medical literature, as well as the experts' opinions and their credibility" supported a special master's determination that a petitioner had not met her burden in demonstrating vaccine causation). Therefore, the Special Master's finding regarding the third element of *Althen* was not arbitrary or capricious, because Petitioner did not establish a proximate temporal relationship by a preponderance of the evidence. Under these circumstances, the court does not "reweigh the evidence." *Cedillo*, 617 F.3d at 1338 (quotation marks omitted).

As to the second element of *Althen*, the Special Master properly considered the logical sequence of cause and effect between the HPV vaccine and Petitioner's ITP. Although the "preponderance of the evidence" standard in Vaccine Program cases is intended to "allow the finding of causation in a field bereft of *complete and direct* proof of how vaccines affect the human body," *Althen*, 418 F.3d at 1280 (italics added), "[m]ere conclusory opinions . . . will not suffice as proof of causation," *Doyle v. Sec'y of Health & Human Servs.*, 92 Fed. Cl. 1, 8 (Fed. Cl. 2010).

Petitioner insists that she did not show symptoms of ITP until after she received the HPV vaccine. Pet. Mem. at 18. But, a simple "proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury." *Moberly*, 592 F.3d at 1323 (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Accordingly, the Special Master properly found that Petitioner did "not provide[ ] a compelling narrative, built from facts set forth in the medical record, establishing a 'logical sequence of cause and effect' associating vaccine to injury." 2/5/2018 Dec. at 24 (quoting *Althen*, 418 F.3d at 1278).

Petitioner also argues that the Special Master neglected to consider that Petitioner's treating physician ordered Petitioner not to have a vaccination "[d]ue to past vaccine reactions." Pet. Mem. at 19 (citing *Kelley*, 68 Fed. Cl. at 98, 100 (giving evidentiary weight to a petitioner's treating physicians' direction that the petitioner not receive another tetanus vaccination); ECF No. 45-1). Therefore, the Special Master must have erred in finding that "[n]o treaters ever proposed a relationship between the HPV vaccine and Petitioner's ITP." Pet. Mem. at 19. But, Petitioner fails to consider that the note from her treating physician was issued in October 2016, when this case was pending before the Special Master. ECF No. 45-1 (note dated and filed on October 11, 2016).

The treating physicians in *Kelley*, unlike any of Petitioner's treating physicians here, "specified [vaccination] as a possible cause [of the petitioner's injury] at both the initial and later phases of [the petitioner's] diagnosis." *Kelley*, 68 Fed. Cl. at 100. So, the United States Court of Federal Claims considered the physicians' notes together with "reliable expert testimony that substantiate[d] [the petitioner's] claim of causation-in-fact." *Id.* In *Andreu v. Secretary of the Department of Health and Human Services*, No. 98-817V, 2008 WL 2009746 (Fed. Cl. 2010), several treating physicians noted the possible causal connection between the petitioner's

vaccination history and injury, as early as a month after the onset of the petitioner's condition. *Id.* at *5–6. But, the petitioner's expert in *Andreu* relied on the treating physicians' notes in concluding that the vaccine at issue caused the petitioner's injury; and, the United States Court of Federal Claims determined that reliance was "reasonable" in "supporting . . . causation." *Id.* at *6. Neither of these cases held that a treating physician's notes alone were "probative" evidence of vaccine causation, as Petitioner suggests. Pet. Mem. at 19; Pet. Reply at 1.

The only indication that any of Petitioner's treating physicians considered the HPV vaccine as a cause of her ITP is the note from Dr. Amin-Chapman, that was written and filed with the court more than three years after the onset of Petitioner's condition and over a year after Petitioner filed the March 10, 2015 Petition. Pet. Mem. at 19; ECF No. 45-1. Moreover, Petitioner's mother testified at the entitlement hearing that Petitioner's treating physicians "wouldn't say" whether "they thought that the Gardasil vaccine caused [Petitioner's] ITP." 6/6/2017 TR at 29. Dr. Shoenfeld agreed that Dr. Amin-Chapman "believ[ed] that [Petitioner] had the ITP as a result of the . . . vaccine," 2/5/2018 Dec. at 24, but the note did not indicate "what contributed to [Dr. Amin-Chapman's] conviction since she didn't write it in the chart before." 6/6/2017 TR at 146–47; 6/7/2017 TR at 255. Therefore, the Special Master's finding that Dr. Amin-Chapman's note warranted less weight than the treating physicians' notes in *Kelley* and *Andreu* was not arbitrary and capricious. In any event, the Special Master's determination that Petitioner did not satisfy the third element of *Althen* was made prior to and independent of his determination regarding the second element. Therefore, even if the Special Master's reasoning regarding the second element might have been different if he relied on Dr. Amin-Chapman's note, the bottom line is Petitioner failed to establish all the elements of *Althen*.

Accordingly, it is not necessary for the court to consider Petitioner's argument that the Government did not make out a case for an "alternative factor" that caused Petitioner's injury. *See Bradley v. Sec'y of Dep't of Health & Human Servs*, 991 F.2d 1570, 1575 (Fed. Cir. 1993) (holding that when a "special master concludes that a petitioner has not demonstrated [causation] by a preponderance of the evidence . . . , the alternative causation theories of [Section 300aa-13(a)(1)(B)] need not be addressed.").

III. CONCLUSION.

For these reasons, Petitioner's March 7, 2018 Motion For Review is denied. The Clerk of Court is directed to enter judgment accordingly.

IT IS SO ORDERED.

s/ Susan G. Braden
SUSAN G. BRADEN
Senior Judge